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THOMPSON COBURN, LLP			HENLEY III, RAYMOND J	
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SUITE 3500				1614
ST LOUIS, MO 63101				

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/083,283	DUGAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on November 1, 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-32 and 56-69 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-32 and 56-69 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 23 February 2002 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/21/02; 9/16/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

**CLAIMS 1-32 AND 56-69 ARE PRESENTED FOR EXAMINATION**

Applicants' "Amendment and Response A" filed November 1, 2004 has been received and entered into the application. Accordingly, claims 33-55 have been canceled.

***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-32 and 56-69 directed to a process for extending the lifespan of a metazoan or metazoan cell in the reply filed on November 1, 2004 is acknowledged.

Insofar as Applicants have canceled the claims directed to the other groups of invention, i.e., groups II and III, the restriction requirement set forth in the previous Office action dated September 30, 2004 is moot and therefore withdrawn.

***Specification***

The abstract of the disclosure is objected to because it is not a single paragraph. "The abstract should be in narrative form and generally limited to *a single paragraph* within the range of 50 to 150 words."(MPEP § 608.01(b)(C)).

Correction is required.

***Claim Rejection - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-32 and 56-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for extending the lifespan of mice which comprises the

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administration of C<sub>3</sub> tris malonic acid C60, does not reasonably provide enablement for extending the lifespan of metazoans or metazoan cells in general which comprises the administration of all of the claimed C<sub>60</sub> compounds, (e.g., claim 1), “a superoxide dismutase-mimetic” (claim 16) or “an antioxidant” (claims 31 and 68) generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

***Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First***

***Paragraph***

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Further, the following excerpts from the MPEP at section 2164.04 are deemed germane:

- “According to *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), *the minimal requirement* is for the examiner to give reasons for the uncertainty of the enablement.”(emphasis added).
- “While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) (a.k.a. the “Wands Factors” as delineated in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) and the evidence as a whole, *it is not necessary to discuss each factor in the written enablement rejection*. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the

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specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims."(emphasis added).

Here, the Examiner is addressing the following "Wands Factors" in order to support his conclusion that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims: (1) breadth of the claims; (2) the state of the prior art; (3) the lack of predictability; (4) the amount of direction provided by the inventor; and (5) the existence of working examples.

***State of the Art and Lack of Predictability Therein***

Concerning the breadth of the instant claims, The present invention relates generally to a method for prolonging the length or duration of the expected lifespan (referred to alternately as "longevity") of metazoans or in metazoan cells, and more particularly, to a method of extending a metazoan's lifespan by administering a composition comprising a therapeutically effective amount of a carboxyfullerene compound, a superoxide dismutase-mimetic or an antioxidant substance. The preferred antioxidant compound is a carboxyfullerene compound of the formula depicted in, for example, Applicants' Figures 1-3.

Applicants' claims further define the above method in terms of the specific compounds, dosage amounts and routes of administration.

While the claim terminology of claim 1 is considered indefinite by the Examiner, (see below), claims 1-5 are representative of the claimed methods and they read as follows:

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1. (original) A process for extending the lifespan of a metazoan or metazoan cells comprising administering to said metazoan a composition comprising a C<sub>60</sub> compound having x pairs of adjacent carbon atoms bonded to two carbons of said C<sub>60</sub> compound wherein said adjacent carbon atom is further bonded to two groups of a general formula -COOH and -R, wherein R is independently selected from the group consisting of -COOH and -H, and wherein x is at least 1.
2. (original) The process of claim 1 where x is 4.
3. (original) The process of claim 2 wherein said composition comprises said C<sub>60</sub> compound, its pharmaceutically acceptable salts and pharmaceutically accepted esters, and a pharmaceutically acceptable carrier, present in said composition in a therapeutically effective amount.
4. (original) The process of claim 1 wherein x is 3.
5. (original) The process of claim 4 wherein said C<sub>60</sub> compound is C<sub>1</sub> tris malonic acid C<sub>60</sub>.

As per the Court's direction in *Marzocchi*, cited above, the objective truth of the statement that the lifespan of a metazoan or a metazoan cell in general may be extended through the administration of s C<sub>60</sub> compound (e.g., claim 1), "a superoxide dismutase-mimetic" (claim 16) or "an antioxidant" (claims 31 and 68) in general is doubted by the Examiner because the art (see the references relied upon *infra*) establishes that lifespan extension may be accomplished in only two specific types of metazoa by only two specific means.

In particular, Roth et al. (European Journal of Clinical Nutrition; cited in Applicants' I.D.S. filed May 21, 2004) teaches "Dietary energy restriction is *the only proven method* for extending lifespan and slowing aging in mammals, while maintaining health and vitality"(emphasis added) (the abstract at page S15, first sentence) and Roth et al. (Annals New York Academy of Sciences; cited in Applicants' I.D.S. filed May 21, 2004) teach "Dietary

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caloric restriction (CR) is the *only* intervention conclusively and reproducibly shown to slow aging and maintain health and vitality in mammals" (abstract at page 305, first sentence).

With respect to rats, Kitani et al. (Life Sciences; cited in Applicants' I.D.S. filed May 21, 2004) teach "There have been many attempts to pharmacologically intervene in the life span of animals. However, *no single pharmaceutical or chemical agent has been shown to be reproducibly effective in this regard*" (emphasis added) (page 281, first sentence following the "Summary" section). Kitani et al. further teach that their "results confirm ...[a] life prolonging effect of (-) deprenyl in aged rats".

Thus, the art recognizes only two means of extending the lifespan of only a select number of metazoans and Applicants' contention that the lifespan of *any* metazoan may be extended through the administration of any of the claimed C<sub>60</sub> compounds, superoxide dismutase-mimetics or antioxidant substances is conspicuously inconsistent with contemporary wisdom in the art of lifespan extension. Based upon the teachings of the art, it would therefore be unpredictable that all metazoans would undergo lifespan extension with the cited compounds.

#### *Examples/Guidance of the Specification*

In the present specification at Example 2 (pages 21-22), Applicants report that in *one* type of metazoan, i.e., mice, lifespan was extended through the administration of *one* carboxyfullerene compound, i.e. C<sub>3</sub> tris malonic acid C<sub>60</sub>. Applicants have provided no objective evidence or a reasoned scientific statement that these specific results may serve as a basis for concluding that similar results would occur in *all* metazoa with *all* of the claimed carboxyfullerene compounds, superoxide dismutase-mimetics or antioxidant substances.

Applicants' statements at page 22, lines 4-9 that:

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"Not to be bound by theory, it is envisioned by the inventors that, the benefits of the instant invention could be utilized to extend the lifespan of all metazoans or metazoan cells, because mice are metazoan organisms. Further, one of ordinary skill in the art would recognize that because the benefits of calorie restriction have been shown in all metazoans tested, that the benefits of the instant invention should farther carry over for all metazoans, including all vertebrates, as well as mammals and more specifically, to humans."

have been carefully considered, but are not seen to diminish the propriety of the Examiner's position. The statements are conclusory in nature and factual supporting evidence has not been presented. Just as such statements would not be probative of unobviousness, see *In re Rijckaert*, 28 USPQ2d 1955 (CAFC 1984) and *In re De Blauwe*, 222 USPQ 191 (CAFC 1984), they are not seen here to be probative of enablement which is commensurate in scope with the claimed subject matter.

Lacking such evidence, and in light of the state of the art, the Examiner is compelled to conclude that the specification is enabling only for a method of extending the lifespan of a mouse which comprises administering to a mouse in need thereof, an amount of C<sub>3</sub> tris malonic acid C<sub>60</sub> effective therefor.

### ***Summary***

As the cited art and discussion above establish, practicing the claimed method in the manner disclosed by Applicants would not imbue the skilled artisan with a reasonable expectation that the lifespan of all metazoans could be extended through the administration of all of the claimed carboxyfullerene compounds, superoxide dismutase-mimetics or antioxidant substances. In order to actually achieve the claimed objective in all of the claimed hosts with all of the claimed pharmacological substances, it is clear from the discussion above that the skilled artisan could not rely on Applicants' disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize and Applicants have failed to demonstrate that all of the

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claimed carboxyfullerene compounds, superoxide dismutase-mimetics and antioxidant substances can extend the lifespan of all metazoans, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention.

None of the claims are limited to a mouse host and to C<sub>3</sub> tris malonic acid C<sub>60</sub> as the active agent. Accordingly, all of the pending claims, i.e., 1-32 and 56-69 are deemed properly rejected.

***Claim Rejection - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**I** Claims 1-4, 6-15, 19-21, 32, 56-59, 61-67 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language employed in claims 1, 19, 32, 56, and 69, i.e., “a C<sub>60</sub> compound having *x* pairs of adjacent carbon atoms bonded to two carbons of said C<sub>60</sub> compound wherein said adjacent carbon atom is further bonded to two groups of a general formula –COOH and –R, wherein R is independently selected from the group consisting of a general formula –COOH and –H, and wherein *x* is at least 1”, does not accurately describe the carboxyfullerene compounds intended for use in the presently claimed invention. In particular, the italicized language above is incorrect in describing a carboxyfullerene compound such as depicted in Figures 2-4.

For the sake of illustrating the ambiguity of the above language, the Examiner has divided up the above language into three conceptual aspects which are paraphrased as follows:

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- (1) "a C<sub>60</sub> compound having x pairs of adjacent carbon atoms";
- (2) "said adjacent pairs of carbon atoms bonded to two carbons of said C<sub>60</sub> compound";

and

- (3) "wherein said adjacent carbon atom is further bonded to two groups of a general formula -COOH and -R"

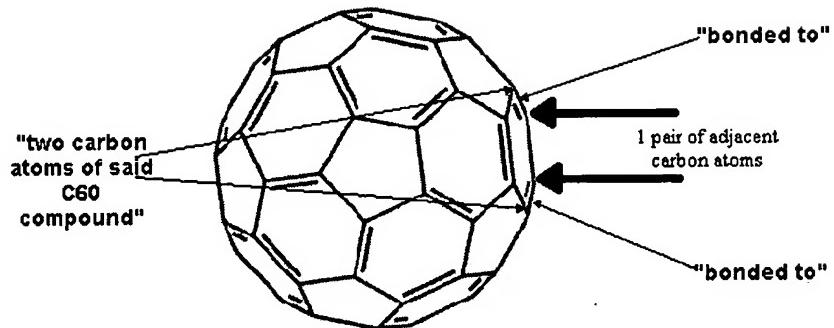
The following depiction of a carboxyfullerene compound is used to point out how the above language would correspond to a given structural element and how such language does not describe the carboxyfullerene compounds intended by Applicants. For the purposes of this illustration, "x" = 1 and "two groups of a general formula -COOH and -R" = (i) -COOH and (ii). -COOH.

*A C<sub>60</sub> compound:*

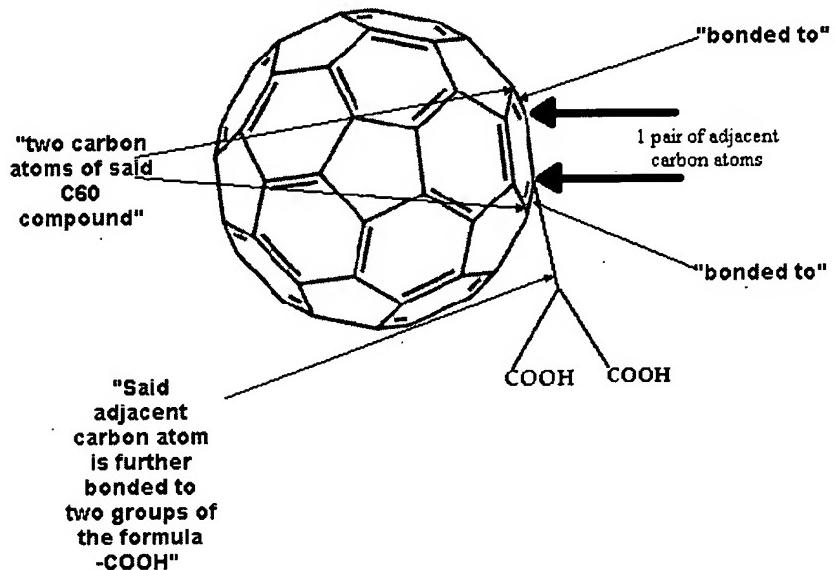


*Fig. 1*

***"A C<sub>60</sub> compound having 1 pair of adjacent carbon atoms; said adjacent carbon atoms bonded to two carbons of said C<sub>60</sub> compound"***



*Fig. 2*  
“Said adjacent carbon atom is further bonded to two groups of the formula –COOH”



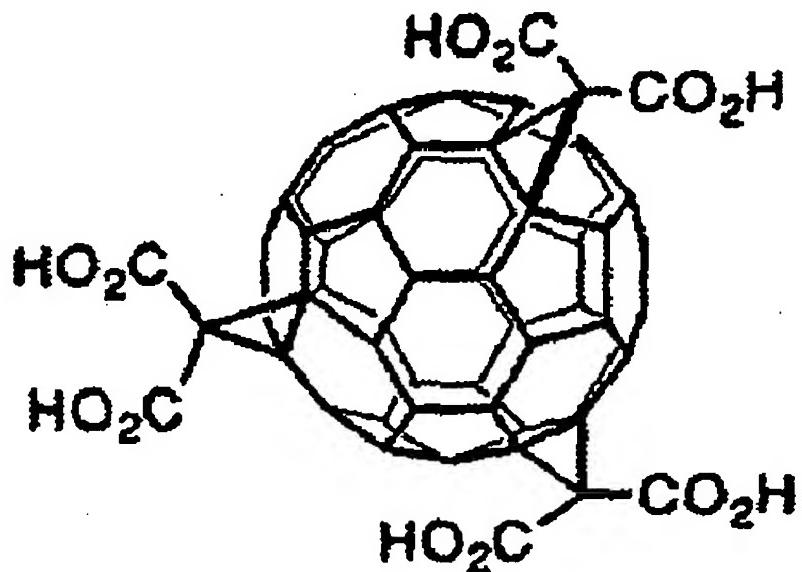
*Fig. 3*

It should also be noted in Fig. 3 that where “said adjacent carbon atom is further bonded to two groups of the formula –COOH”, such bond need not be a direct bond as illustrated. Indeed, such may include instances beyond the scope of the present disclosure where the –COOH groups are bonded to the fullerene compound indirectly, such as through any number of

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moieties including phenyl rings, pyridine rings, other fullerene compounds, cyclopentanohydrophenanthrene rings, etc.

The following is an example of a carboxyfullerene compound intended by Applicants, i.e., C<sub>3</sub> tris malonic acid C<sub>60</sub> as shown in Applicants' "Figure 2", compound "C3":



*Fig. 4*

As illustrated by the Examiner, the compound of Fig. 3, *supra*, meets the requirements set forth in present claims 1, 19, 32, 56, and 69, but clearly does not represent a carboxyfullerene compound intended by Applicants, such as that shown in Fig. 4, *supra*.

Accordingly, the claims are deemed properly rejected as being indefinite for not particularly pointing out the subject matter that applicants regard as their invention. See *In re Prater*, 415 F.2d at 1404, 162 USPQ at 550 (a claim that reads on subject matter beyond the applicant's invention fails to comply with 35 U.S.C. §112).

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***II*** Claims 8, 10, 20, 25, 27, 57, 63 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in the expressions "about 3 mg/kg", "about 15 mg/kg" and "about 4" in these claims is a relative term which renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (MPEP 2173).

Because the term "about" would invite subjective interpretations of whether or not a particular dosage amount or compound is included by or excluded from the present claims, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims do not meet the requirements of 35 U.S.C. § 112, second paragraph.

#### *Scope and Content of the Claims*

The present invention relates generally to a method for prolonging the length or duration of the expected lifespan (referred to alternately as "longevity") of metazoans or in metazoan

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cells, and more particularly, to a method of extending a metazoan's lifespan by administering a composition comprising a therapeutically effective amount of an antioxidant. The preferred antioxidant compound is a carboxyfullerene compound of the formula depicted in, for example, Applicants' Figures 1-3.

Applicants' claims further define the above method in terms of the specific compounds, dosage amounts and routes of administration.

While the claim terminology of claim 1 is considered indefinite by the Examiner, (see above), claims 1-5 are representative of the claimed methods and they read as follows:

1. (original) A process for extending the lifespan of a metazoan or metazoan cells comprising administering to said metazoan a composition comprising a C<sub>60</sub> compound having x pairs of adjacent carbon atoms bonded to two carbons of said C<sub>60</sub> compound wherein said adjacent carbon atom is further bonded to two groups of a general formula -COOH and -R, wherein R is independently selected from the group consisting of -COOH and -H, and wherein x is at least 1.
2. (original) The process of claim 1 where x is 4.
3. (original) The process of claim 2 wherein said composition comprises said C<sub>60</sub> compound, its pharmaceutically acceptable salts and pharmaceutically accepted esters, and a pharmaceutically acceptable carrier, present in said composition in a therapeutically effective amount.
4. (original) The process of claim 1 wherein x is 3.
5. (original) The process of claim 4 wherein said C<sub>60</sub> compound is C<sub>7</sub> tris malonic acid C<sub>60</sub>.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-32 and 56-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lei et al. (U.S. Patent No. 6,777,445, cited by the Examiner) and Stedman's Medical Dictionary (cited by the Examiner) in view of Chiang (U.S. Patent No. 5,648,523, cited by the Examiner), Choi et al. (U.S. Patent No. 6,265,443, cited by Applicants; see form PTO/-A820 filed May 21, 2002) and WO 97/46227 ("WO '227", PCT counterpart of Choi et al. '443, cited by Applicants; see form PTO/SB/08A filed September 16, 2004).

Lei et al. teach a method for the treatment of viral and/or bacterial infections which comprises the administration of a therapeutically effective amount of a composition comprising a pharmaceutically acceptable carrier and a fullerene compound or derivatives thereof, such as salts, wherein the compound is of the formula: F[C-X(Y)<sub>n</sub>]<sub>m</sub> in which F is a fullerene core; C is a

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carbon atom attached to two vicinal carbon atoms of the fullerene skeleton at the [6,6] ring junction and form a fused cyclopropane ring; X and Y are identical or different and may be – CO<sub>2</sub>H; n is 0 or 1; and m is 1-10. See the abstract; col. 3, lines 8-64; and col. 4, line 58 – col. 5, line 11. The water-soluble carboxylic acid of fullerene derivative with C<sub>3</sub> symmetry [C<sub>60</sub>(C<sub>3</sub>)], i.e., wherein X and Y are independently –CO<sub>2</sub>H; n is 1; and m is 3 (i.e., the compound of present claims 5 and 60) is specifically disclosed at col. 8, lines 33-40.

Lei et al. further teach that the therapeutically effective amount may be from about 10 to about mg/kg body weight per day (col. 3, lines 55-56) or from 0.001 to about 100 mg/kg (col. 13, line 58). The composition may be administered intravenously, intramuscularly, subcutaneously or orally (col. 5, lines 62-64) to a host which is a human or “animals of any kind”, including dogs, pigs, sheep, horses, cows, cats, zoo animals or mice (col. 8, lines 5-12). It is noted from Stedman’s Medical Dictionary at page that “Metazoa” is defined as “[a] subkingdom of the kingdom of Animalia, including all multicellular animal organisms in which the cells are differentiated and form tissues; distinguished over the subkingdom of Protozoa, or unicellular animal organisms.” (page 956, col. 1). Thus, the claimed host, i.e., “metazoan or metazoan cells” (e.g., claim 1) is taught by Lei et al.

The differences between the above and the claimed subject matter lie in that Lei et al. fail to disclose:

- (1) that the lifespan of a metazoan or metazoan cell may be extended with the presently claimed carboxyfullerene compounds (e.g., claim 1);
- (2) pharmaceutically accepted esters of the fullerene compounds (e.g., claim 3); and
- (3) “a superoxide-mimetic” (claim 16) or “an antioxidant compound” (claims 31 and 68).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because of the following reasons.

(1) Lei et al. teach that viral and/or bacterial infections may be effectively treated (see, for example, the abstract) and specifically teach at col. 12, lines 38-54 (and Figure 8) that in mice “[v]arious doses of C<sub>60</sub> were administered before Group A Streptococci injections...[t]he results indicate that administration of C<sub>60</sub> increased mouse survival.” Also, at col. 13, line 36 – col. 14, line 10 (and Figure 13) the patentees teach that mice were protected from a bacterial infection that was known to be fatal through the administration of a fullerene compound. Specifically, the patentees disclose that “[i]t is known that *E. coli*-induced meningitis is fatal” (col. 13, line 38) and that “treatment employing the 40 mg/kg dose protected the mouse from *E. coli*-induced meningitis” (col. 13, lines 59-61).

Therefore, the patentees teach that the lifespan of mice having fatal bacterial infections was successfully and unequivocally extended through the administration of an effective amount of a fullerene compound and such would have clearly motivated one of ordinary skill in the art to employ a fullerene compound for the purposes claimed. While a carboxyfullerene compound of the instant claims, (C<sub>3</sub> tris malonic acid C<sub>60</sub>, for example), is not expressly disclosed in the above cited sections, i.e., col. 12, lines 38-54 (and Figure 8) and col. 13, line 36 – col. 14, line 10 (and Figure 13), one of ordinary skill in the art would have been motivated to employ carboxyfullerene compounds of the instant claims for the purposes disclosed by the patentees because not only are the present carboxyfullerene compounds generically taught at col. 4, line 58

– col. 5, line 11, but the carboxyfullerene specie as in present claims 5 and 60, i.e., C<sub>3</sub> tris malonic acid C<sub>60</sub>, is disclosed in an exemplary manner as being a preferred carboxyfullerene compound for the purposes taught by the patentees and claimed by Applicants (Lei et al. at col. 8, lines 33-48).

(2) As evinced by Chiang (U.S. Patent No. 5,648,523; col. 8, lines 8-12), Choi et al. (U.S. Patent No. 6,265,443; Figures 2B and 3B and col. 3, lines 46-53) and WO '227 (Figures 2-3 and page 21, lines 23-25), carboxyfullerene esters were known to the skilled artisan as being pharmaceutically acceptable fullerene derivatives. One of ordinary skill in the art would have been motivated to employ the carboxyfullerene esters for the purposes taught by Lei et al. because Lei et al. expressly disclose “[t]he invention contemplates the use of *any fullerene*, including, but not limited to, a buckminsterfullerene or fullerenol. *All* fullerenes and fullerene derivatives, isomers, salts and enantiomers are referred to herein as “fullerene”(emphasis added; col. 4, lines 59-63).

(3) The expressions “a superoxide-mimetic” (claim 16) or “an antioxidant compound” (claims 31 and 68) represent no more than statements of intended function and, because such expressions do not impart any feature to the claimed carboxyfullerene compounds not present in the carboxyfullerene compounds of the references relied upon, they fail to impart patentable moment to the claimed subject matter.

Accordingly, for the above reasons, the claims are deemed properly rejected.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-32 and 56-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-33 of copending Application No. 10/373,425 (Attorney Docket No. 53047/39519).

Although the conflicting claims are not identical, they are not patentably distinct from each other because as shown in Figures 2-3 of the co-pending application, (the co-pending specification is properly relied upon here<sup>1</sup> as a dictionary for the meaning of the expression “an e,e,e malonic acid/acetic acid tri-adduct of buckminsterfullerene of the general formula...a hydrogen” [co-pending claim 22]), there is overlap in the scope of compounds employed in the present claims and those of the instant claims thus rendering this aspect of the presently claimed subject matter obvious to one of ordinary skill in the art.

The present claims further differ from the co-pending claims in that the co-pending claims fail to refer to the carboxyfullerene compounds as “a superoxide dismutase-mimetic” (claim 16) or “an antioxidant” (claims 31 and 68). However, such are statements of intended use and do not impart any further physical or otherwise material feature to the present compounds

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<sup>1</sup> “The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 164 USPQ 619, 622 (CCPA 1970).” See MPEP § 804(II)(B)(1).

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that is not found in the compounds of the co-pending claims. Accordingly, the subject matter of the present claims and of the co-pending claims would have been obvious, each set of claims over the other.

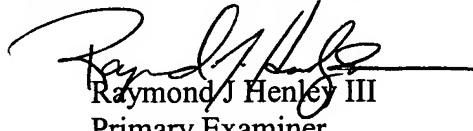
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

January 11, 2005